

REMARKS

Claims 1-20 are pending. Applicant hereby amends claim 19 without conceding to the Examiner's rejection and without prejudice. No new matter has been added. Claim 20 has been canceled without prejudice. Applicant notes and thanks Examiner for indicating that claim 20, if rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraph and to include all of the limitations of the base claim, would be allowable. Claims 1-20 have been rejected.

Specification

The Examiner requested that Lucidol, Carbopol, Versene, Puramex ZN, Glycopure, Finsolve TN, Arlacel, Brij, Tween, and Steareth be capitalized because the Examiner believes them to be trademarks. Lucidol, Carbopol, Versene, Puramex, Arlacel, Brij, and Tween have been noted as a trademarks and capitalized and an "®" has been added. However, Glycopure, Finsolve and Steareth are not trademarks according to the US Patent and Trademark Office database and are terms recognized by one of ordinary skill in the art. Accordingly, Applicant believes that the objection has been addressed and should be removed.

Drawings

The Examiner has indicated that color drawings are not accepted unless a petition is filed under 35 U.S.C. §1.84(a)(2). Herewith attached as Exhibit A is a copy of the petition filed concurrently under 35 U.S.C. §1.84(a)(2) along with the following requirements: (1) 3 sets of color drawings; (2) an amendment to the specification to reference the color drawings; (3) the fee set forth in 37 C.F.R. §1.17(h); and (4) a black and white copy of the colored drawings.

35 U.S.C. § 112, 2nd paragraph

Claims 1-20 have been rejected under 35 U.S.C. §112, 2nd paragraph, as being indefinite. Specifically, the Examiner has rejected claims 1-18 because "the expressions 'low enough', 'substantially uniformly absorb', 'substantially retained' and 'substantially uniformly delivered' do not set forth the meaning of the claim." The Examiner requests clarification.

Applicant respectfully traverses this rejection. The terms outlined by the Examiner are discussed within the instant specification and are described in such a manner that one of ordinary skill in the art would understand the meaning of the terms used.

The term "low enough" is discussed throughout the specification and specifically at page 4, paragraph 13, which states, "the viscosity of the composition is carefully adjusted to be low enough that the composition will permeate the matrix of the pad's fibers and be held on the pad by capillary action. However, the viscosity must not be so low that the composition is so thin that it drains off the pad prematurely. On the other hand, if the viscosity is too high, not only will the composition fail to be taken into the pad's fibers' matrix, it will tend to be released from the surface of the pad to the walls of the container, and remain there, unavailable for application to the patient's skin." Page 4, paragraph 13; *see also* page 3, paragraph 10. Further, the specification shows tests that were performed to determine viscosities that meet the claim element. *See* Test 1, 2, and 4, pp. 9-13. Based upon use of the term "low enough" and the disclosure throughout the specification, one of ordinary skill in the art would understand the meaning of the term and the scope of the claims as a whole.

The term "substantially uniformly absorb" is discussed in the specification and specifically at page 8, paragraph 33, which states, "the composition may be an emulsion which is substantially absorbed via capillary action to the pad, and the composition remains on the pad in the container and a therapeutic amount of medication in the composition is discharged to the skin upon wiping the pad across the skin." Page 8, paragraph 33. Additionally, dermatologically active ingredients "do not preferentially migrate or adsorb from the composition . . . onto or into the pad, and therefore does not result in an uneven concentration of the dermatologically active ingredient in the composition versus the pad." Page 3, paragraph 11. The specification also discusses the tests performed and shows photos to show the uniform application of the composition from the pad to the skin. *See* Tests 2 and 3. To achieve such uniformity, one of ordinary skill in the art would understand the meaning of the term "substantially uniformly absorb" and the scope of the claims as a whole.

The term "substantially retained" is discussed throughout the specification and specifically at page 3, paragraph 11, which states, "[t]he composition is retained by the pad

preferentially over the container." The specification also discusses tests performed to determine whether the BPO in the composition was excessively transferred from the pad to the inside of the container. Page 9, paragraph 37 – page 10, paragraph 38, and Test 1. Given the disclosure provided in the specification, one of ordinary skill in the art would understand the meaning of the term and the scope of the claims as a whole.

The term "substantially uniformly delivered" is discussed throughout the specification and specifically at page 4, paragraph 14, which states, "[u]se of the present invention by wiping the pad across the skin results in a transfer to the skin of the dermatologically active ingredient, meaning that the skin is substantially uniformly medicated." Further, the specification includes photos of skin with BPO delivered from the invention and discusses tests performed to determine whether the composition applies uniformly to the skin via the pad. See page 10, paragraphs 39-44, and Tests 2 and 3. Based upon the disclosure in the specification, including the experiments performed to illustrate the substantially uniform delivery of a composition, one of ordinary skill in the art would understand the meaning of the term and the scope of the claims as a whole.

Therefore, one of ordinary skill in the art, armed with the specification, would understand the meaning of the claims with the terms discussed above. As such, Applicant believes the 35 U.S.C. §112, 2nd paragraph rejection has been addressed and should be removed.

Claims 19 and 20 have been rejected under 35 U.S.C. §112, second paragraph, because the claims "contain the trademark/trade name 'steareth'." As discussed above, steareth is not a trademark according to the US Patent and Trademark Office database and is a term known by those of ordinary skill in the art. Accordingly, Applicant believes that the rejection has been addressed and should be removed.

35 U.S.C. § 102(b)

Claims 1-3, 6, 7, and 13-18 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 5,562,642 ('642 patent). Applicant respectfully traverses this rejection for at least the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegual Bros. v.*

Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, if a prior art reference does not teach each and every claim element, it does not anticipate the claim.

The '642 patent fails to teach each and every claim element. The Examiner himself agrees that "US '642 does not teach the claimed particle size and viscosity." No where in the '642 patent is the viscosity of the composition disclosed. The '642 patent mentions viscosity with respect to the emollient oils that may be used, but not with respect to the viscosity for the composition that is applied to the pad. See column 12, lines 39-53. Therefore, since the '642 patent does not teach each and every element of the claimed invention, it does not anticipate these claims. As such, the Applicant requests the rejection be removed.

35 U.S.C. § 103(a)

U.S. 5,562,642

Claims 4, 5, and 8-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the '642 patent. Specifically, the Examiner states that "[t]he claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests the low viscosity of the liquid composition as implied by the flowability of the composition in order to be absorbed into the non-woven pad." Further, the Examiner states that, "US '642 does not teach the claimed particle size and viscosity."

Applicants respectfully traverse this rejection. To establish prima facie obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As discussed above, the '642 patent fails to teach the viscosity of the composition that is to be applied to the pad. Further, the specific viscosity values and particle sizes provided in the claims are not found in the '642 patent, which the Examiner explicitly points out. The Examiner also argues that the low viscosity of the liquid can be implied by the flowability of the composition to be absorbed into the non-woven pad. However, there is no discussion explicitly or implicitly regarding the viscosity of the

composition that is added to the pad, nor can the "flowability" suggested by the Examiner imply that the viscosity is such that the composition is substantially uniformly absorbed onto the pad and be substantially retained on the pad not the container. There is not at teaching or suggestion to modify the '642 patent, therefore, the Examiner has failed to meet the burden necessary to establish a case of prima facie obviousness. If the Examiner is relying on his own knowledge, Applicant invites him to provide a declaration pursuant to 37 CFR §1.104(d)(2). Absent such declaration, Applicant requests withdrawal of the rejection.

The Examiner also states that the particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. Applicant respectfully disagrees. The Examiner may not merely disregard claimed elements by stating that he or she think they do not impart patentability. Claim 1, which claims 4, 5, and 8-12 depend from, recite that "the composition has a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action and be substantially retained on the pad not the container" as an element of the claim. Additional listed elements in dependent claims, such as particle size, also impart patentability. Also, the claims taken as a whole, as required by 35 U.S.C. §103, are not obvious if the cited reference does not teach each and every claim element. Therefore, since the specific values outlined in the claims are not found in the '642 patent and the '642 patent fails to even teach or suggest the viscosity or particle size of the claimed invention, the reference does not make the claimed invention obvious, and Applicant respectfully requests the rejection be removed.

U.S. 6,183, 766 in view of U.S. 5,562,642, U.S. 6,861,397, and U.S. 5,821,237

Claim 19 has been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. 6,183,766 ('766 patent) in view of the '642 patent and further in view of U.S. 6,861,397 ('397 patent) and U.S. 5,821,237 ('237 patent).

Applicant respectfully traverses this rejection. As discussed above, to establish a prima facie case of obviousness the following must be shown: (1) the prior art references must teach or suggest all of the claimed elements; (2) there must be a reasonable expectation of success; and (3) there must be some suggestion or motivation to modify or combine the references. MPEP §2143. The Examiner cites four references in an attempt to show that the present invention is

obvious. However, the cited references when combined fail to meet the standard for establishing a prima facie case of obviousness.

The four references fail to teach or even suggest all of the claimed elements. Specifically, the references fail to teach the composition having a low enough viscosity for the composition to substantially uniformly absorb onto the pad via capillary action and be substantially retained on the pad not the container. The '766, '642' and '397 patents do not mention or discuss the viscosity of the composition that is to be applied to the pad. The viscosity pointed out by the Examiner in the '642 patent (col. 12, lines 46-60 and col. 14, lines 38-40) pertains to the viscosity of emollient oils that may possibly be added to the composition and not to the viscosity of the composition. Further, the second location cited by the Examiner to show the viscosity element pertains to polymeric waxes. Column 14, lines 38-40. This citation in no way teaches or suggests the viscosity of the composition.

The '237 patent mentions viscosity, but actually teaches away from a low viscosity and teaches using thickeners to achieve a high viscosity. For example, the '237 patent states that, "[p]referred emulsions have a high viscosity, of from about 10,000 to about 300,000 centipoise, more preferably from about 20,000 to about 200,000 centipoise, most preferably from about 50,000 to about 150,000 centipoise." Column 13, lines 25-28. Further support for the '237 patent teaching away from a low viscosity is found in the values provided in the instant specification. For example, at page 11, paragraph 46, the viscosity values for the example compositions are illustrated. Example 1 showed a viscosity range of 2000-2800 cps; Example 2 showed a viscosity range of 2000-2400 cps; Example 3 showed a viscosity range of 2000-2500 cps; and Examples IV-VII showed viscosities ranging from 2200 to 6600 cps. Therefore, the '237 patent teaches away from composition having a low enough viscosity for the composition to substantially uniformly absorb onto the pad via capillary action and be substantially retained on the pad not the container.

Further, in order for the Examiner to make his 35 U.S.C. §103 argument, he had to find four references to even attempt to meet each and every claim element. Despite this effort, the Examiner has fallen short of showing a prima facie case of obviousness. The reliance on so many references, coupled with the fact that not all of the elements are taught and the lack of

motivation or suggestion to combine the references, shows that the claimed invention is not obvious in light of the cited references.

Therefore, since the cited references do not teach each and every element and there is no motivation or suggestion to combine the references, Applicant respectfully requests the rejection be removed.

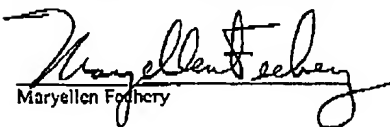
CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests consideration and allowance of the pending claims. Finally, Applicant respectfully submits a request for a personal interview with the Examiner, in order to further resolve any outstanding issues.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of this application, or credit any overpayment, to Deposit Account No. 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire pendency of this application.

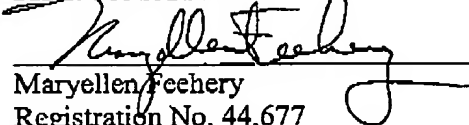
I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/613,698 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 571-273-8300 on the date shown below.


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Respectfully submitted,

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EXHIBIT

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